DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

July 31, 1996

Our Reference Number: 95-1295

Howard R. Six, Ph.D.
Connaught Laboratories, Inc.
Route 611
P.O. Box 187
Swiftwater, PA 18370-0187

Dear Dr. Six:

The Supplement to your Product License Application for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed (DTaP), to include the use of this product for the primary series in infants and children as an additional indication, has been approved.

This product is currently licensed in the U.S. as a fourth and/or fifth dose in children 15 months to seven years of age (prior to the seventh birthday) who have previously received a 3 or 4 dose series of Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed (Whole Cell Pertussis). With the approval of this supplement, Tripedia® (DTaP) may now also be used for a three dose primary series in children at least six weeks of age and for a fourth dose in children who have received 3 doses of DTaP or DTP.

This approval also includes a single dose vial presentation. The dating period for this product in the single dose vials shall be 18 months from the date of manufacture when stored at 2-8°C. The dating period of a final combination is based on the component with the shortest dating period and/or the first valid potency test, whichever is the shortest [21 CFR 610.50(a) and 21 CFR 610.53(b)].

We acknowledge the following commitments made by you in your correspondence to us:

1. You have agreed to continue to collect data to support the safety of Tripedia® as the fifth dose after 4 previous doses of Tripedia® (your letters dated July 12, 1996, and July 24, 1996). This study should be conducted under an IND. After collection, these data should be submitted in the form of a Supplement to your Product License Application along with revised labeling, to support this indication.

2. You have committed to conducting postmarketing surveillance studies (your letter dated July 24, 1996).

a. You have committed to continue monitoring for at least 5 years and to the administration of approximately 60,000 doses to children under 12 months of age during the period of surveillance.

b. You have committed to reporting safety results annually. The first report should be submitted no later than August 1, 1997.

3. You have committed to examining the duration of protection after a 4 dose series with Tripedia® by following a cohort from the German case-control study for a period of five years (your letter dated July 18, 1996). A study proposal should be submitted to the Center for Biologics Evaluation and Research no later than December 31, 1996.

This information will be placed on file in your product license application.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information. In addition, please submit three copies of the introductory advertising and promotional labeling. You may wish to submit the proposed materials in draft form with a form 2567 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike, Rockville, MD 20852-1448. Promotional claims should be consistent with, and not contrary to, approved labeling. No comparative claims or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation.

It is requested that adverse experience reports for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed, be submitted in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and the Vaccine Injury Act, and that distribution reports be submitted as described in 21 CFR 600.81. Since your product is categorized as a vaccine, these reports should be submitted to the Vaccine Adverse Event Reporting System (VAERS) using the pre-addressed form VAERS-1.

Sincerely yours,

M. Carolyn Hardegree

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research